

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**RECKITT BENCKISER LLC,**

*Plaintiff,*

**-VS-**

**AUROBINDO PHARMA LIMITED and  
AUROBINDO PHARMA USA, INC.,**

*Defendants.*

Civil Action No. 1:14-cv-01203-LPS

REDACTED -- PUBLIC VERSION

**PLAINTIFF RECKITT BENCKISER'S OPPOSITION TO DEFENDANTS' MOTION  
FOR LEAVE TO MOVE FOR SUMMARY JUDGMENT**

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Plaintiff Reckitt Benckiser, LLC (“Reckitt”) respectfully opposes defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.’s (“Aurobindo”) motion for leave to file a motion for summary judgment.

## **I. INTRODUCTION AND SUMMARY OF ARGUMENT**

Having already tried to move for summary judgment under the guise of a motion to strike [D.I. 92-93], Aurobindo’s current motion for leave to file a motion for summary judgment is yet another attempt to circumvent the Court’s claim construction process and to avoid expert discovery and trial. Reckitt opposed the motion to strike [D.I. 103] and for similar reasons, Aurobindo’s motion for leave to file for summary judgment should likewise be denied.

In short, there is a genuine issue of material fact concerning how Aurobindo’s ANDA product actually releases its active ingredients. Aurobindo asserts that [REDACTED]

[REDACTED]

[REDACTED] What Aurobindo’s ANDA *contains*, however, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Reckitt has now provided detailed expert analysis of [REDACTED]

[REDACTED] *See, e.g.* Ex. 1, Reckitt’s Expert Report on Infringement<sup>1</sup>, at ¶¶ 46-53, 83-93, 186-190. Reckitt’s expert has also performed independent testing of samples of Aurobindo’s drug product confirming [REDACTED]

[REDACTED] *See, e.g., id.* at [REDACTED]

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<sup>1</sup> Exhibit 1 is attached to the Declaration of B. Satra, filed concurrently.

¶¶ 54-74, 94-100, 170-173, 186-190. That evidence disproves Aurobindo's characterizations and proves that its drug product infringes the asserted patent claims in this case.

## II. NATURE AND STAGE OF PROCEEDINGS

Reckitt filed suit against Aurobindo for the infringement of U.S Patent Nos. 6,372,252 (the "'252 Patent"), 6,955,821 (the "'821 Patent") and 7,838,032 (the "'032 Patent") (the "Patents-in-Suit") on or about September 17, 2014.<sup>2</sup> During fact discovery, which closed on July 27, 2016, Reckitt produced detailed infringement claim charts setting forth an element-by-element analysis of its infringement theories. The parties also exchanged written discovery and thousands of pages of documents. Subsequently on August 9, 2016, the Court conducted a *Markman* hearing concerning four terms in dispute, and has yet to issue its claim construction ruling. The parties also served opening expert reports on August 24, 2016, including the opening Infringement Report of Reckitt's expert Mario A. Gonzalez, Ph.D. detailing how Aurobindo's ANDA product meets every element of the asserted claims of the '821 and '032 patents. The parties will be serving rebuttal expert reports on September 14, 2016. Both the Court's *Markman* Order and expert discovery, coupled with the disclosures made during fact discovery, will bear on the ultimate issue of Aurobindo's infringement.

## III. LEGAL STANDARD

"[S]ummary judgment is proper if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (noting that summary judgment may be

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<sup>2</sup> On August 24, 2016, the Court granted the parties' joint motion to dismiss the '252 Patent from the case. (D.I. 111.)

entered “after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case”).

Summary judgment can only be granted, if after viewing the facts in the light most favorable to Reckitt, as the non-moving party, there is no genuine issue of material fact as to whether Aurobindo’s ANDA product infringes the Patents-in-Suit. *See ART+COM Innovationpool GmbH v. Google Inc.*, No. 14-217-RGA, 2016 U.S. Dist. LEXIS 56501, at \*27 (D. Del. Apr. 28, 2016) (“summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is covered by the claims (as construed by the court)”). By the same token, a motion for leave to seek summary judgment should be denied when the existence of factual disputes give rise to issues that do “not appear to be amenable to resolution on summary judgment.” *Intellectual Ventures I LLC v. Symantec Corp.*, No. 13-440-LPS, 2014 U.S. Dist. LEXIS 134255, at \*13-14 (D. Del. Sept. 24, 2014).

#### **IV. ARGUMENT**

##### **A. The Record Establishes Genuine Issues of Material Fact as to Aurobindo’s Infringement.**

Aurobindo’s motion is predicated on its argument that [REDACTED]

[REDACTED] Aurobindo ignores the language of the asserted claims and any claim construction analysis, as the law requires, and instead only characterizes the patents in general.<sup>3</sup> In fact, each of the asserted patent claims requires certain quantities and/or forms/formulations that release guaifenesin at particular times or in certain amounts such that

<sup>3</sup> For example, Aurobindo asserts that [REDACTED]

they create certain pharmacokinetic levels in patients after administration. *See, e.g.*, '821 patent claims 1 and 29, '032 patent claim 1. Aurobindo's ANDA product satisfies those claims based upon [REDACTED]

Aurobindo asserts that its [REDACTED]

[REDACTED] As noted below, Reckitt and its infringement expert dispute this. As a result, there are genuine issues of material fact as to the alleged non-infringement of the ANDA product, and thus, the issue of non-infringement cannot be resolved by summary judgment.

Reckitt and its experts have reviewed Aurobindo's ANDA and conducted testing of samples of Aurobindo's ANDA product. As detailed in Reckitt's infringement contentions and now in Reckitt's expert report, [REDACTED]

[REDACTED] *See, e.g.*, Ex. 1 at ¶¶ 46-74, 83-100, 170-173. As detailed in Reckitt's infringement claim charts,

[REDACTED]

(D.I. 93, Aurobindo Ltr. Br., Ex. A, Infringement Claim Chart, p. 2 (emphasis supplied); *see also, e.g.*, Ex. 1 at ¶¶ 46-53, 83-93, 170-173.) Further, after studying these indications from Aurobindo's own clinical data, physical samples of Aurobindo's ANDA product were then

separately analyzed by Reckitt's experts through extensive testing, [REDACTED]

[REDACTED]

[REDACTED] For example:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(D.I. 93, Aurobindo Ltr. Br., Ex. A, Infringement Claim Chart, p. 2 (emphasis supplied).)

Reckitt's infringement expert report further analyzes Aurobindo's ANDA and samples of Aurobindo's ANDA product, detailing these tests and the evidence for how and why Aurobindo's product satisfies each and every limitation of the asserted claims. *See, e.g.*, Ex. 1 at ¶¶ 46-74, 83-100, 170-173, 186-190.

This evidence, both from Aurobindo's own ANDA data and from separate testing of product samples, further explained and supported by expert opinion established a genuine



dispute of material fact. Certainly viewed in the light most favorable to Reckitt, as the non-moving party, these genuine issues of material fact as to Aurobindo's infringement preclude summary judgment for Aurobindo as a matter of law under Rule 56. *See ART+COM Innovationpool*, 2016 U.S. Dist. LEXIS 56501, at \*27.

**B. Contrary to Aurobindo's Assertions, *Watson* Does Not Preclude Reckitt from Using Evidence Concerning Dissolution Testing or Plasma Concentration Data to Prove the Presence of an Immediate Release Quantity.**

Reckitt's analysis and testing have not been precluded by the prior litigation involving the '252 patent. Contrary to Aurobindo's arguments (D.I. 94, ¶¶ 5-10), the disclosures of the ANDA itself and Reckitt's expert's opinion do not [REDACTED]

[REDACTED] The Federal Circuit in the prior *Watson* decision did not make any holdings against the use of dissolution testing or plasma concentration data. (*See id.*) The language referenced by Aurobindo from that decision expressly states that any actual IR release properties in the *Watson* product were unavailing only because the presence of an IR formulation did not inform whether the product contained a "discrete IR portion." (*See id.* at ¶ 10, citing to *Reckitt Benckiser, Inc. v. Watson Labs., Inc.*, 430 F. App'x 871, 877-78 (Fed. Cir. 2011).) For all the reasons presented at the *Markman* Hearing, unlike the '252 patent at issue in *Watson*, the '821 and '032 patents at issue here have no separate or discrete "portion" requirement in their asserted claims. The point of distinction the Federal Circuit discussed, therefore, has no relevance here and in no way impacts the weight of Reckitt's infringement evidence and expert opinions.<sup>4</sup>

<sup>4</sup> Moreover, unlike in the *Watson* case, [REDACTED]

*See, e.g.,* Ex. 1 at ¶¶ 47, 50-52, 61-69, 72-73.

**C. Reckitt's Testing Evidence Is Appropriate Evidence of Infringement Under Federal Circuit Precedent.**

Despite Aurobindo's assertion that the "ANDA directly addresses the question of infringement," testing of the ANDA product may be used to prove infringement and Aurobindo's reliance on *Bayer AG v. Elan Pham, Res. Corp.* 212 F.3d 1241, 1250 (Fed. Cir. 2000) is misplaced. (See D.I. 94, ¶¶ 9-10.) In *Bayer*, the court rejected attempts to undercut what an ANDA disclosed by casting doubts on the underlying data from the "biobatch" preparation of the subject product. *Bayer AG*, 212 F.3d at 1249-50. The court refused to allow inconsistent arguments that the biobatch could not have possessed certain qualities. *See id.* Here in contrast, Reckitt's tests do not purport to establish inconsistencies with Aurobindo's recipe as disclosed in its ANDA. Rather, Reckitt notes that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See, e.g.,* Ex. 1 at ¶¶ 46-74, 83-100, 170-173.

Because Aurobindo's ANDA product specification [REDACTED]

[REDACTED] additional testing of the ANDA product samples is completely appropriate. *See, e.g., Bayer*, 212 F.3d at 1250 (discussing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1564-70 (Fed. Cir. 1997) (holding testing of ANDA samples appropriate because ANDA specification did not foreclose and instead permitted infringement possibilities)); *Janssen Prods., L.P. v. Lupin Ltd.*, No. 2:10-cv-05954

(WHW), 2014 U.S. Dist. LEXIS 155248, at \*89-92 (D.N.J. Mar. 12, 2014) (denying summary judgment and rejecting defendants’ reliance on *Bayer*, the Court held that where the ANDA specification does not foreclose infringement, “strict reliance on the ANDA content is not applicable” and the court may “consider not just the ANDA itself, but also the materials submitted [by the ANDA applicant] to the FDA, and other pertinent evidence provided[] by the parties” including expert testing of the ANDA product) (citations and internal quotations omitted).

Aurobindo cannot credibly contend that [REDACTED] [REDACTED] (D.I. 94, ¶¶ 9-10.) Rather, as noted above, there are genuine issues of material fact as to Aurobindo’s non-infringement of the Patents-in-Suit that cannot be resolved upon a motion for summary judgment. *See Stambler v. RSA Sec.*, No. 01-065-SLR, 2003 U.S. Dist. LEXIS 1548, at \*9-10 (D. Del. Jan. 29, 2003) (summary judgment of non-infringement “inappropriate” where “each of the ten non-infringement arguments . . . for the ‘148 and ‘302 patents require defendants to have prevailed on claim construction terms (when they did not) or involve genuine issues of material fact for the jury to resolve”).<sup>5</sup>

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<sup>5</sup> Aurobindo contends that the “only other issue for the Court to resolve is [REDACTED] [REDACTED] (D.I. 94, ¶¶ 11-12; *see, e.g.*, D.I. 51, pp. 8-9.) For the reasons set forth by Reckitt during claim construction, Aurobindo’s arguments should be rejected. (*See, e.g.*, D.I. 61, pp. 10-12.)

**V. CONCLUSION**

Because there are genuine issues of material fact as to Aurobindo's alleged non-infringement, Reckitt respectfully requests that Aurobindo's motion for leave to seek summary judgment be denied.

Date: August 25, 2016

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Pilar G. Kraman, hereby certify that on September 1, 2016, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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